

Remarks

I. Status and Nature of the Amendments

Claims 1-24 are pending. Claims 5-11, 15-24 have been withdrawn as directed to a non-elected invention.

II. The Requirement for Restriction of the Claims

The Examiner has advised Applicant that the requirement for restriction issued by the prior Examiner has been reconsidered. The Examiner has advised that the present application contains four independent and distinct inventions:

- I. Claims 1-4 and 12-14, drawn to a method for assaying one or more target analytes, classified in class 435, subclass 7.1;
- II. Claims 1, 2, 5 and 12-14, drawn to a method for assaying one or more target analytes comprising molecules that sterically interfere with the ability of a ligand to bind with analyte, classified in class 436, subclass 537;
- III. Claims 6-11, drawn to a method of assaying analyte comprising chemical interference, classified in class 435, subclass 283.1; and
- IV. Claims 15-24, drawn to a composition for assaying a target analyte, classified in class 436, subclass 518.

The Examiner has accordingly advised that restriction of the claims is appropriate.

Applicant herewith responds to the Restriction requirement by electing to prosecute in this application **Invention I** (claims 1-4 and 12-14). Claims directed to the non-elected invention have been withdrawn. Applicant's election is made with traverse.

Applicant respectfully submits that the method claims of supposedly independent and distinct Inventions I, II, and III clearly should be examined together, and that the stated basis for restricting the claims conflates the concepts of independent and distinct invention with that of genus/species relationships. In this regard, it is respectfully submitted that an examination of the claims of the supposedly independent and distinct Inventions I, II, and III reveals that these claims all relate to a unifying inventive concept:

A method of assaying a target analyte by providing a binding ligand of the target analyte and a solid support under conditions that hinder with the ability of the target analyte to bind to the ligand

Contrary to the Examiner's statement, supposed Group I (claims 1-4 and 12-14) do not require "pores" that sterically interfere with target analyte binding. The term pores does not appear in claim 1 or claim 12. The use of "pores" (recited in claim 3) to mediate such interference is a *species* of the invention that is generically claimed in claim 1. Thus, no basis whatsoever is seen for restriction between the claims of supposedly independent and distinct Inventions I and II.

Claims 6-11 relate to an alternative *species* invention of hindering the ability of the target analyte to bind to the ligand: using chemical interference. Claims 6-11 do not relate to an invention that is "independent" and "distinct" from the inventions of claims 1-5 and 12-14.

Importantly, all of the method claims operate on precisely the same principle: "determining, for such target analyte(s), the presence, absence, activity or concentration of said target analyte(s), by determining the extent of binding between said target analyte and said solid-support-bound binding ligand of said target analyte." Reconsideration of the requirement for restriction between the claims of Inventions I, II and III is earnestly requested.

The Examiner has advised that the invention of the claims of group IV are independent and distinct from the invention of claims 1-5 and 12-14 because:

“the product group IV can be used in either [sic] of the materially different processes of groups I-III” (Emphasis Added).

Applicant submits that such a conclusion misapprehends the criteria for restriction. Restriction is permissible only where the product claims (Group IV) can be used in a process that is materially different *from those claimed in the application*. It is submitted to be improper (and illogical) to use the ability of the *claimed* products to be used in the *claimed* methods as a basis for concluding that such products and processes are “independent and distinct” inventions warranting restriction.

In this regard, the Examiner’s attention is respectfully drawn to MPEP § 802.01 which instructs that restriction is permitted only when two claimed inventions are independent and distinct. MPEP § 802.01 further advises that the term “independent” means that:

“there is no disclosed relationship between the two inventions claimed, that is, they are unconnected in design, operation, and effect. For example, a process and an apparatus incapable of being used in practicing the process are independent inventions.” [Emphasis Added]

MPEP § 802.01 further instructs that inventions that are related are not independent, and specifically instructs that a process and an apparatus for its practice are related inventions that are not independent. Thus, applicants claimed methods and compositions are related, non-independent inventions. In order to properly restrict between two “related” inventions, the inventions must be *distinct* – i.e., not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) ...” MPEP § 802.01. The term “materially different” obviously denotes “materially different

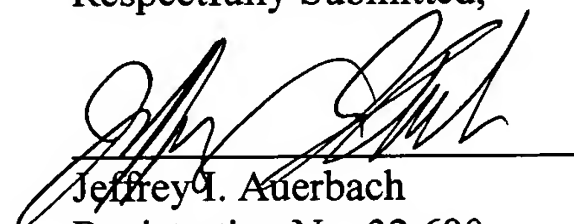
from the processes being claimed." It is respectfully submitted that the restriction requirement should be withdrawn.

Applicant requests that the Examiner reconsider and withdraw the restriction requirement in light of the above remarks. In the event that the restriction requirement is nevertheless made final, Applicant respectfully requests that the Examiner consider rejoining the withdrawn claims to the application when Allowable subject matter is found with respect to the elected invention.

Having now responded to all of the Examiner's Objections, Applicant respectfully submits that the present application is in condition for Examination, and earnestly solicits early notice of favorable action. The Examiner is respectfully invited to contact the undersigned with respect to any issues regarding this application.

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Respectfully Submitted,


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